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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,871	10/11/2006	Yasumichi Fukuda	2006_1305A	1343

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WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
WASHINGTON, DC 20006-1021

EXAMINER
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STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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12/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/590,871

### Applicant(s)

FUKUDA ET AL.

### Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on November 16, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/28/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

**Claims 1-9 are pending in the application.**

***Election/Restrictions***

Applicant's election of Group I {Claims 1-9 - drawn to products of formula (1) wherein X is CH<sub>2</sub>, CHF, CF<sub>2</sub> or CHOH} in the reply filed on November 16, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group I is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s),

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there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on November 16, 2007.

It is suggested that in order to advance prosecution, the non-elected subject matter be cancelled when responding to this Office Action.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statement filed on August 28, 2006.

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### ***Specification***

The amendment filed August 28, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change made on pages 34-35, paragraph [0071].

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

Claims 7-9 are objected to for being substantial duplicates of claim 1. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

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allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. §706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, "general" should be deleted because it implies compounds that are not embraced by formula (1). See claims 2-5, all occurrences, for same.

Claim 1 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other

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periods may be used elsewhere in the claims except for abbreviations {i.e., "1 to 3." }. See claim 4 for same.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villhauer {U.S. Pat. 6,432,969} and Villhauer {WO 98/19998}, each taken alone or in combination with each other.

***Determination of the scope and content of the prior art (MPEP***

***§2141.01)***

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Applicant claims pyrrolidine compounds. Each of Villhauer '969 {see entire document; particularly columns 2, 3, 8 and 15; and especially Compound dd) in column 24} and Villhauer '998 (see entire document; particularly pages 2-4; and especially Compound 29 on page 12) teach pyrrolidine compounds that are structurally similar to the instant claimed compounds.

***Ascertainment of the difference between the prior art and the claims***

***(MPEP §2141.02)***

The difference between the compounds of Villhauer '998 and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

The difference between the compounds of Villhauer '969 and the compounds instantly claimed is that of homology {the Y variable in Villhauer represents (4-**pentyl**bicyclo[2.2.2]oct-1-yl)amine instead of a (4-**butyl**bicyclo[2.2.2]oct-1-yl)amine as embraced by the instant claims}.



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***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., inhibiting DPP-IV). Further, to those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950).

One skilled in the art would thus be motivated to prepare products embraced by Villhauer '998, or homologs of the compounds taught by Villhauer '969, to arrive at the instant claimed products with the expectation of obtaining additional beneficial products

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which would be useful in treating, for example, arthritis. Since both Villhauer references teach pyrrolidine compounds that are structurally similar to each other and are useful in treating similar diseases/disorders such as arthritis, the combination of the Villhauer references would also teach the instant claimed invention. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

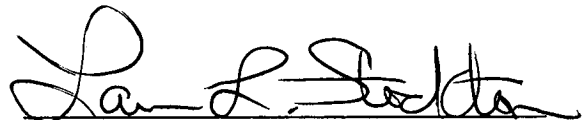
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for

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unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

December 20, 2007